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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/020,596  | 12/07/2001  | Michael M. Becker    | GP123-02.UT         | 6565             |
| 21365   | 7590        | 04/26/2006           | EXAMINER            |                  |
| GEN PROBE INCORPORATED<br>10210 GENETIC CENTER DRIVE<br>SAN DIEGO, CA 92121 |             |                      | SISSON, BRADLEY L   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1634                |                  |

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/020,596             | BECKER, MICHAEL M.  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Bradley L. Sisson      | 1634                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25,27-32,34,36 and 61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25,27-32,34,36 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |



## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1, which claim 16 depends from, stipulates that one is to add dissociating agent “in an amount sufficient to dissociate said polymer from said complex after said probe and said target nucleic acid have had sufficient time to associate in said sample.” Such language clearly requires that a complex comprising the polycationic polymer be formed, else, one cannot dissociate it from the hybridized nucleic acids. Given such, the aspect of claim 16 reciting that “a complex comprising said polymer is formed in said sample under said conditions” is not deemed to further limit claim 1.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-25, 27-32, 34, 36, and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the



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claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) (“the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed”). Thus, an applicant complies with the written-description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572.

3. As presently worded, the method of claims 1-5, 7-25, 27-32, 34, and 61 fairly encompasses the use of a polycationic polymer at virtually any concentration. Similarly, the method of claims 1-6, 8-25, 27-32, 34, and 61 and where the polycationic polymer has virtually any mass. A review of the disclosure finds support for using the polymer within a range of from “about 10  $\mu$ M to about 1000  $\mu$ M” (page 30, lines 20-23), and where the polycationic polymer has a mass of from “at least 10,000 Da” to “less than about 300,000 Da” (page 30, lines 24-29).

4. It is further noted that the method of claims 1, 3-25, 27-32, 34, 36, and 61 fairly encompass having cationic monomers (can be found in the polymer), and the phosphate groups of the nucleic acids, are in relative equal numbers. As set forth at page 30, second paragraph, the aspect of having both cationic monomers and phosphate groups present in relative the same amounts could well lead to precipitation of the polynucleotide from solution, which “is undesirable.”



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A review of the specification fails to locate an adequate written description of alternative concentrations, masses, and molar ratios of polycationic polymers to be using. Such non-disclosure of the full scope of the claimed invention does not reasonably suggest that applicant had possession of the invention at the time of filing. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

5. In view of the limited disclosure, as well as the explicit statements of issues/non-working embodiments to be avoided, applicant is urged to consider adding the limitations of claims 2, 6, and 7 to that of claim 1.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 17 is confusing as to what applicant is referring to when the phrase "a plurality of polymers" is used. Given that DNA, RNA, as well as the polycationic polymer are all polymers



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of one stripe or another, it is less than clear if the term “polymer” in this instance is referring to any one of these identified polymers, or whether a previously unidentified polymer is being contemplated here.

9. Similar confusion exists with respect to claim 18. As required in claim 1, the polycationic polymer is to complex with the nucleic acids, be it target or probe, or a duplex structure comprising both. If these are the only polymers present, and a covalent linkage between said polymers is formed, it is less than clear how a “dissociation” agent would remove the polycationic polymer and not also disrupt the probe-target duplex structure.

10. Claim 21 is confusing with respect to just how much of an “increase” of association between probe and target needs to actually take place. As presently worded, claim 21 recites the limitation of “at least about 2-fold greater,” however, the term “about has been construed to include values below 2, including 1, which would not be an increase in association. A review of the disclosure fails to find a definition of “about.” Accordingly, and in the absence of convincing evidence to the contrary, the metes and bounds of claim 21 cannot be readily determined and as such, it is deemed indefinite.

### ***Conclusion***

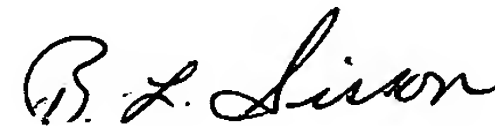
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.



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12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
19 April 2006